

UNITED STATES PATENT APPLICATION

FOR

**DIETETIC FOOD COMPOSITION AND DIETETIC METHOD USING
SUCH COMPOSITION**

601-017c1-101801

This application claims the benefit of priority from the continuation-in part application serial number 09/333,097 filed on June 15, 1999 entitled "Dietetic food composition and dietetic method using such composition" based on the parent application Serial No. 09/225,819 filed on January 5, 1999 which claims priority to European Patent Application No. 98830365.7 filed on June 16, 1998 and European Patent Application No. 99201794.7 filed on June 4, 1999.

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FIELD OF THE INVENTION

This invention relates to the sector of the food and dietetic industry.

In particular, the invention relates to a substitute food composition for cereal flours in general and for wheat flour in particular, and foods which can be prepared using this composition.

The invention also relates to a method for controlling the body weight of an individual.

BACKGROUND ART

It is well known that in the developed nations and even in the developing nations the percentage of individuals having excess weight if not obesity problems is constantly and progressively increasing. This has important consequences both for the health of individuals and for the overall health cost of the various nations, because it has been amply demonstrated that obesity or even being overweight are important associated causes of cardiovascular and metabolic diseases, such as myocardial infarction, stroke, type II diabetes, etc.

The dietetic measures generally proposed by dieticians to combat and/or prevent excess weight mainly consist of low-calorie or low-fat regimes.

Another widely recommended measure for the control of body weight which is even advocated by the mass media (periodicals, television, etc.) is adoption of the famous "Mediterranean diet", based on foods rich in complex carbohydrates such as pasta, rice, bread and the like.

It is, however, a fact that the widespread use of low-calorie diets and the Mediterranean diet has not in fact resulted in any statistically significant change in the percentage of obese or overweight persons; there is instead a progressive increase in this percentage.

A low-calorie diet can in fact have some temporary effect on reducing body weight but this cannot be maintained for a long period, either because it results in general weakening of the body, or because over the long term it is rejected by the individual because of the monotony of the flavours of the food making it up (essentially meat, fish and greens).

The so-called "Mediterranean diet" is in fact only suitable for maintaining the right weight and the right form in individuals who are engaged in vigorous physical activity. Persons who are engaged in essentially sedentary work can on the other hand experience an increase in weight and an accumulation of lipids when they feed themselves on foods based essentially on carbohydrates.

SUMMARY OF THE INVENTION

The problem underlying this invention is that of providing a diet/foodstuff which allows obese or merely overweight persons to recover their ideal weight by eliminating excess lipids and to maintain such an ideal weight over a long period of time. All this without the persons having to subject themselves to a low-calorie diet and to suffer the deprivation of foodstuffs which it is difficult to do without over long periods, such as pasta, bread and bakery products in general.

Such a problem is solved according to the invention by a food composition in the form of a flour comprising at least 50% of protein, up to 15% of carbohydrates and from 35 to 50% of plant fibres.

The diet according to the present invention is characterized by totally or partially eliminating carbohydrates from overweight persons' diet. Said kind of diet is usually known in the art as ketogenic diet. The ketogenic diet satisfies always one's appetite and brings always to a loss in weight, but may also cause several side-effects such as, for instance, hyperuricemia, hyperglycemia, hypercholesterolemia, hypertriglyceridemia, hepatic-pancreatic alterations, mental disorders, etc.

Therefore, a further problem underlying this

invention is that of providing a composition for preventing and treating the above mentioned side-effects which can occur in a ketogenic diet such as the one according to the present invention.

Said further problem is solved by a pharmaceutical composition as recited in the appended claims.

DETAILED DESCRIPTION OF THE INVENTION

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The present invention relates to a food composition in the form of a flour, The carbohydrate content of the food composition according to the present invention is preferably less than 10%, advantageously less than 5%.

The proteins are preferably selected from the group comprising gluten, soya proteins, milk proteins in particular from soya milk without lactose, animal proteins obtained from meat or dried or smoked fish, egg albumen and yolk, wheat proteins, wheat germ, rice germ, soya bean protein, pea protein.

The plant fibres are preferably selected from the group comprising cereal fibres, in particular wheat, maize and oats, wheat, maize and soya bean brands, vegetable fibres, in particular tomato, spinach, inulin, acacia and fruit fibres, in particular oranges and apples.

The food composition according to the present invention may additionally comprise vegetal fat, in

particular from coconut and soya bean and animal lipids, in particular from yolk, cream and whole milk.

Said food composition may further comprise flours, in particular flours selected from the group consisting of tender wheat flour and drum wheat flour.

Both the proteins and the plant fibres are used in a finely divided form and mixed in suitable ratios to produce flours which can be used as substitutes for wheat flour in the preparation of foods such as pasta, bread, bread sticks, bakery products and pastries.

This invention also relates to a method for improving the appearance of a person by achieving a loss of weight which is beneficial from the aesthetic point of view, this method comprising the elimination from the said person's diet of all carbohydrate-based foods and their replacement with foods obtained using the flours described above.

Advantageously such a method provides for the initial use of flours having the lowest carbohydrate content possible, in any event a content of not more than 5% by weight.

A certain although minimum carbohydrate content is always present in the flours according to the invention because commercially available plant fibres always have a small residual glucide content. Once the desired

group consisting of 1-phenyl-2-diethylamine-1-propanone hydrochloride (diethylpropione chlorohydrate), fenfluramine chlorohydrate and D-fenfluramine chlorohydrate. A preferred dosage of the anorectic agent is from 2 mg to 35 mg per day for an adult of a weight of about 70 kg.

The lipolytic agent is preferably selected from the group consisting of analogues of tiroxine, most preferably said agent is 3,5,3'-triiodiotiroacetic acid. A preferred dosage of the lipolytic agent is from 0,2 mg to 0,8 mg per day for an adult of a weight of about 70 kg.

The method according to the invention therefore provides for an individual who intends to lose weight to eliminate all carbohydrate-rich foods such as bread, pasta, sweets and bakery products in general from his diet and to replace them by "facsimile" foods obtained using the flours described above, using non-sugar sweeteners in the case of sweets.

The above-mentioned flours may be used in the same way as wheat flour. To prepare bread for example, such flours are made into a dough with water and yeast, and possibly salt, lard, olive oil or other optional ingredients, allowed to rise and then baked in an oven at the same temperature at which bread is baked.

Similarly, in order to prepare sweets such as tarts,

biscuits or the like, the flours are made into a dough with butter or margarine or similar fats, eggs, yeast if desired and other optional ingredients, with the addition of non-glucide sweeteners (e.g. saccharine) and baked in an oven in the same way as traditional sweets.

Those who intend to retain their ideal weight by following the method according to the invention should also abstain from consuming fruits which are rich in sugars, sweetened drinks, etc.

As said above, a pharmaceutical composition is also provided for preventing or treating the side-effects which can occur in a ketogenic diet.

In particular, said pharmaceutical composition A comprises an hypocholesterolemic agent, a hypotriglyceridemic agent, a lipasic and proteasic agent, a hypoglycemic agent and a hydrocoleretic agent.

The hypocholesterolemic agent is preferably selected from the group consisting of 2-[alpha-methyl-(trifluoromethyl)phenethylamine]-ethanolbenzoate (benfluorex) and 3-alpha-7B-dihydroxy-5B-colan-24 oic acid (ursodesoxycolic acid).

The hypotriglyceridic agent is preferably 2-[alpha-methyl-(trifluoromethyl)phenethylamine]-ethanolbenzoate (benfluorex) which is preferably present in a global amount from 7% to 23% in weight with respect of the total

amount of the composition A.

The lipase and protease agent is preferably total lyophilized pancreas (Pancreatine IX F.U.) which is preferably present in an amount from 27% to 43% in weight with respect of the total amount of the composition A.

The hypoglycemic agent is preferably selected from the group consisting of biguanides, said biguanides being preferably 1,1-dimethylbiguanide (metformine) which is preferably present in an amount from 36% to 41% in weight with respect to the total amount of the composition A.

The hydrocoleretic agent is preferably selected from the group consisting of 3,7,12-triose-5B-colan-24 oic acid (Na dehydrocolate) and 3alfa-7B-dihydroxy-5B-colan-24 oic acid (ursodesoxycolic acid). When Na dehydrocolate is present, it is preferably in an amount from 9% to 14% in weight with respect of the total amount of the composition A. When ursodesoxycolic acid is present, it is preferably in an amount from 14% to 17% in weight with respect to the total amount of the composition A.

The composition may additionally comprise an hypouricemic agent. Said agent is preferably centella asiatica purified triterpenes which may be preferably present in a ratio from 0,04:1 to 0,5:1 in weight with respect to the total amount of the composition A.

Moreover, the composition may comprise a radical

scavenger agent. Preferably said agent is selenium which may be preferably present in a ratio from 0,0001:1 to 0,0003:1 in weight with respect to the total amount of the composition A.

The composition may also comprise a sympatholytic agent. Said agent is preferably methyl 17-alfa-hydroxy-yohimbane-16-alfa-carboxylate (yohimbine) which may be preferably present in a ratio from 0,0009:1 to 0,007:1 in weight with respect of the total amount of the composition A.

The composition may additionally comprise a sympathicomimetic agent. Said agent is selected from the group consisting of phendimetrazine bitartrate and phendimetrazine pamoate, which may be preferably present in a ratio from 0,004:1 to 0,1:1 in weight with respect to the total amount of the composition A..

Furthermore, the composition may comprise at least one vitamin, preferably said at least one vitamin is selected in the group consisting of vitamin A, vitamin B₁, vitamin B₆, vitamin E and vitamin C.

When vitamin A is present, it is in a ratio from 0,4:1 to 1,8:1 in weight with respect to the total amount of the composition A.

When vitamin B₁ is present, it is in a ratio from 0,002:1 to 0,007:1 in weight with respect to the total

amount of the composition A.

When vitamin B₆ is present, it is in a ratio from 0,04:1 to 0,2:1 in weight with respect to the total amount of the composition A.

When vitamin E is present, it is in a ratio from 0,09:1 to 1:1 in weight with respect to the total amount of the composition A.

When vitamin C is present, it is in a ratio from 0,09:1 to 0,3:1 in weight with respect to the total amount of the composition A.

The composition A may further comprise at least one adjuvant selected from the group consisting of a sedative-ansiolytic agent, an anorectic agent and a lipolytic agent.

The sedative-ansiolytic agent is preferably a benzodiazepine, most preferably 7-chloro-2,3-dihydro-2-oxo-5-phenyl-1H-1,4-benzodiazepine (dipotassium chlorazepate) which is preferably present in a ratio from 0,0004:1 to 0,03:1 in weight with respect to the total amount of the composition A.

The anorectic agent is preferably selected from the group consisting of 1-phenyl-2-diethylamine-1-proparone hydrochloride (diethylpropione chlorohydrate), fenfluramine chlorohydrate, D-fenfluramine chlorohydrate. Said anorectic agent is preferably present in an amount

from 0,002:1 to 0,1:1 in weight with respect to the total amount of the composition A.

The lipolytic agent is preferably selected from the group consisting of analogues of tiroxine, most preferably said agent is 3,5,3'triiodiotiroacetic acid which is preferably present in a ratio from 0,0002:1 to 0,003:1 in weight with respect to the total amount of the composition A.

All the above agents which can be comprised into the composition A, are usually commercially available.

In particular, diethylpropione chlorohydrate is an anorectic agent used as adjuvant in the treatment of obesity. It shows the same activity of the amphetamine, but with less effects upon the CNS (Central Nervous System) and upon cardiovascular system. Therefore, it is preferable for hypertensive, cardiopath, diabetic and elderly persons.

Fenfluramine and D-fenfluramine are anorectic agents used as adjuvants in the treatment of obesity, which show a psycho-stimulating effect.

Benfluorex is an hypocholesterolemic and hypotriglyceridemic agent which also shows anorectic and hypoglycemic activities.

Centella asiatic is a light diuretic, antirheumatic and peripheral vasodilative agent used in the treatment

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pregnancy.

Vitamin B₆ is used in the treatment and prophylaxis of pyridoxine deficit, in the treatment of anaemia, convulsions, gravidic and radiant hyperemesis in the prophylaxis of peripheral neuritis.

Vitamin E is used to cure hypovitaminosis, lipid malabsorption and is used as anti-oxidant for premature infants.

Vitamin C is used to treat ascorbic acid deficit.

Triiodotiroacetic acid is a thyroid hormone which shows a lipolytic activity.

Dipotassium chlorazepate is a sedative-ansiolytic agent which has the pharmacological activity of the benzodiazepine.

Fendimetrazine bitartrate and pamoate are sympathomimetic agent. They also shows a central anorectic activity.

The composition of the drug and the doses will vary with the conditions of the patients to be treated. Therefore, specific dosages regiments should be adjusted to the individual need and the professional judgement of the person administering or supervising the administration of the aforesaid composition. The dosages may be administered at once or may be divided into a number of smaller doses to be administered at varying

intervals of time.

Said agents have been selected to be combined in a synergetic way such that to improve their single pharmaceutical properties and, at the same time, not interfering one with the others.

The advantage provided by said pharmaceutical composition is that of preventing or treating the above mentioned side-effects which can occur in a diet lacking in carbohydrates.

Moreover, by means of a combination of the food composition and of the pharmaceutical composition according to the invention, it is always possible to loose weight without the person having to suffer deprivation of foodstuffs such as pasta, bread and bakery product.

The pharmaceutical composition of the invention may additionally contain excipient and optionally other auxiliary agents, if necessary.

The composition of the present invention can be administered in different pharmaceutical formulation, the precise nature of which will depend upon the chosen route of administration.

Thus, solid compositions for orally administration include compressed tablets, dispersible powders, granules and capsules.

FOI b7D b7C b7E b7F b7G b7H b7I b7J b7K b7L b7M b7N b7O b7P b7Q b7R b7S b7T b7U b7V b7W b7X b7Y b7Z b7AA b7AB b7AC b7AD b7AE b7AF b7AG b7AH b7AI b7AJ b7AK b7AL b7AM b7AN b7AO b7AP b7AQ b7AR b7AS b7AT b7AU b7AV b7AW b7AX b7AY b7AZ b7BA b7BB b7BC b7BD b7BE b7BF b7BG b7BH b7BI b7BJ b7BK b7BL b7BM b7BN b7BO b7BP b7BQ b7BR b7BS b7BT b7BU b7BV b7BW b7BX b7BY b7BZ b7CA b7CB b7CC b7CD b7CE b7CF b7CG b7CH b7CI b7CJ b7CK b7CL b7CM b7CN b7CO b7CP b7CQ b7CR b7CS b7CT b7CU b7CV b7CW b7CX b7CY b7CZ b7DA b7DB b7DC b7DD b7DE b7DF b7DG b7DH b7DI b7DJ b7DK b7DL b7DM b7DN b7DO b7DP b7DQ b7DR b7DS b7DT b7DU b7DV b7DW b7DX b7DY b7DZ b7EA b7EB b7EC b7ED b7EE b7EF b7EG b7EH b7EI b7EJ b7EK b7EL b7EM b7EN b7EO b7EP b7EQ b7ER b7ES b7ET b7EU b7EV b7EW b7EX b7EY b7EZ b7FA b7FB b7FC b7FD b7FE b7FF b7FG b7FH b7FI b7FJ b7FK b7FL b7FM b7FN b7FO b7FP b7FQ b7FR b7FS b7FT b7FU b7FV b7FW b7FX b7FY b7FZ b7GA b7GB b7GC b7GD b7GE b7GF b7GG b7GH b7GI b7GJ b7GK b7GL b7GM b7GN b7GO b7GP b7GQ b7GR b7GS b7GT b7GU b7GV b7GW b7GX b7GY b7GZ b7HA b7HB b7HC b7HD b7HE b7HF b7HG b7HH b7HI b7HJ b7HK b7HL b7HM b7HN b7HO b7HP b7HQ b7HR b7HS b7HT b7HU b7HV b7HW b7HX b7HY b7HZ b7IA b7IB b7IC b7ID b7IE b7IF b7IG b7IH b7IJ b7IK b7IL b7IM b7IN b7IO b7IP b7IQ b7IR b7IS b7IT b7IU b7IV b7IW b7IX b7IY b7IZ b7JA b7JB b7JC b7JD b7JE b7JF b7JG b7JH b7JI b7JJ b7JK b7JL b7JM b7JN b7JO b7JP b7JQ b7JR b7JS b7JT b7JU b7JV b7JW b7JX b7JY b7JZ b7KA b7KB b7KC b7KD b7KE b7KF b7KG b7KH b7KI b7KJ b7KK b7KL b7KM b7KN b7KO b7KP b7KQ b7KR b7KS b7KT b7KU b7KV b7KW b7KX b7KY b7KZ b7LA b7LB b7LC b7LD b7LE b7LF b7LG b7LH b7LI b7LJ b7LK b7LL b7LM b7LN b7LO b7LP b7LQ b7LR b7LS b7LT b7LU b7LV b7LW b7LX b7LY b7LZ b7MA b7MB b7MC b7MD b7ME b7MF b7MG b7MH b7MI b7MJ b7MK b7ML b7MN b7MO b7MP b7MQ b7MR b7MS b7MT b7MU b7MV b7MW b7MX b7MY b7MZ b7NA b7NB b7NC b7ND b7NE b7NF b7NG b7NH b7NI b7NJ b7NK b7NL b7NM b7NO b7NP b7NQ b7NR b7NS b7NT b7NU b7NV b7NW b7NX b7NY b7NZ b7OA b7OB b7OC b7OD b7OE b7OF b7OG b7OH b7OI b7OJ b7OK b7OL b7OM b7ON b7OO b7OP b7OQ b7OR b7OS b7OT b7OU b7OV b7OW b7OX b7OY b7OZ b7PA b7PB b7PC b7PD b7PE b7PF b7PG b7PH b7PI b7PJ b7PK b7PL b7PM b7PN b7PO b7PP b7PQ b7PR b7PS b7PT b7PU b7PV b7PW b7PX b7PY b7PZ b7QA b7QB b7QC b7QD b7QE b7QF b7QG b7QH b7QI b7QJ b7QK b7QL b7QM b7QN b7QO b7QP b7QQ b7QR b7QS b7QT b7QU b7QV b7QW b7QX b7QY b7QZ b7RA b7RB b7RC b7RD b7RE b7RF b7RG b7RH b7RI b7RJ b7RK b7RL b7RM b7RN b7RO b7RP b7RQ b7RR b7RS b7RT b7RU b7RV b7RW b7RX b7RY b7RZ b7SA b7SB b7SC b7SD b7SE b7SF b7SG b7SH b7SI b7SJ b7SK b7SL b7SM b7SN b7SO b7SP b7SQ b7SR b7SS b7ST b7SU b7SV b7SW b7SX b7SY b7SZ b7TA b7TB b7TC b7TD b7TE b7TF b7TG b7TH b7TI b7TJ b7TK b7TL b7TM b7TN b7TO b7TP b7TQ b7TR b7TS b7TT b7TU b7TV b7TW b7TX b7TY b7TZ b7UA b7UB b7UC b7UD b7UE b7UF b7UG b7UH b7UI b7UJ b7UK b7UL b7UM b7UN b7UO b7UP b7UQ b7UR b7US b7UT b7UU b7UV b7UW b7UX b7UY b7UZ b7VA b7VB b7VC b7VD b7VE b7VF b7VG b7VH b7VI b7VJ b7VK b7VL b7VM b7VN b7VO b7VP b7VQ b7VR b7VS b7VT b7VU b7VV b7VW b7VX b7VY b7VZ b7WA b7WB b7WC b7WD b7WE b7WF b7WG b7WH b7WI b7WJ b7WK b7WL b7WM b7WN b7WO b7WP b7WQ b7WR b7WS b7WT b7WU b7WV b7WW b7WX b7WY b7WZ b7XA b7XB b7XC b7XD b7XE b7XF b7XG b7XH b7XI b7XJ b7XK b7XL b7XM b7XN b7XO b7XP b7XQ b7XR b7XS b7XT b7XU b7XV b7XW b7XZ b7YA b7YB b7YC b7YD b7YE b7YF b7YG b7YH b7YI b7YJ b7YK b7YL b7YM b7YN b7YO b7YP b7YQ b7YR b7YS b7YT b7YU b7YV b7YW b7YX b7YY b7YZ b7ZA b7ZB b7ZC b7ZD b7ZE b7ZF b7ZG b7ZH b7ZI b7ZJ b7ZK b7ZL b7ZM b7ZN b7ZO b7ZP b7ZQ b7ZR b7ZS b7ZT b7ZU b7ZV b7ZW b7ZX b7ZY b7ZZ b7AA b7AB b7AC b7AD b7AE b7AF b7AG b7AH b7AI b7AJ b7AK b7AL b7AM b7AN b7AO b7AP b7AQ b7AR b7AS b7AT b7AU b7AV b7AW b7AX b7AY b7AZ b7BA b7BB b7BC b7BD b7BE b7BF b7BG b7BH b7BI b7BJ b7BK b7BL b7BM b7BN b7BO b7BP b7BQ b7BR b7BS b7BT b7BU b7BV b7BW b7BX b7BY b7BZ b7CA b7CB b7CC b7CD b7CE b7CF b7CG b7CH b7CI b7CJ b7CK b7CL b7CM b7CN b7CO b7CP b7CQ b7CR b7CS b7CT b7CU b7CV b7CW b7CX b7CY b7CZ b7DA b7DB b7DC b7DD b7DE b7DF b7DG b7DH b7DI b7DJ b7DK b7DL b7DM b7DN b7DO b7DP b7DQ b7DR b7DS b7DT b7DU b7DV b7DW b7DX b7DY b7DZ b7EA b7EB b7EC b7ED b7EE b7EF b7EG b7EH b7EI b7EJ b7EK b7EL b7EM b7EN b7EO b7EP b7EQ b7ER b7ES b7ET b7EU b7EV b7EW b7EX b7EY b7EZ b7FA b7FB b7FC b7FD b7FE b7FF b7FG b7FH b7FI b7FJ b7FK b7FL b7FM b7FN b7FO b7FP b7FQ b7FR b7FS b7FT b7FU b7FV b7FW b7FX b7FY b7FZ b7GA b7GB b7GC b7GD b7GE b7GF b7GG b7GH b7GI b7GJ b7GK b7GL b7GM b7GN b7GO b7GP b7GQ b7GR b7GS b7GT b7GU b7GV b7GW b7GX b7GY b7GZ b7HA b7HB b7HC b7HD b7HE b7HF b7HG b7HH b7HI b7HJ b7HK b7HL b7HM b7HN b7HO b7HP b7HQ b7HR b7HS b7HT b7HU b7HV b7HW b7HX b7HY b7HZ b7IA b7IB b7IC b7ID b7IE b7IF b7IG b7IH b7IJ b7IK b7IL b7IM b7IN b7IO b7IP b7IQ b7IR b7IS b7IT b7IU b7IV b7IW b7IX b7IY b7IZ b7JA b7JB b7JC b7JD b7JE b7JF b7JG b7JH b7JI b7JJ b7JK b7JL b7JM b7JN b7JO b7JP b7JQ b7JR b7JS b7JT b7JU b7JV b7JW b7JX b7JY b7JZ b7KA b7KB b7KC b7KD b7KE b7KF b7KG b7KH b7KI b7KJ b7KK b7KL b7KM b7KN b7KO b7KP b7KQ b7KR b7KS b7KT b7KU b7KV b7KW b7KX b7KY b7KZ b7LA b7LB b7LC b7LD b7LE b7LF b7LG b7LH b7LI b7LJ b7LK b7LL b7LM b7LN b7LO b7LP b7LQ b7LR b7LS b7LT b7LU b7LV b7LW b7LX b7LY b7LZ b7MA b7MB b7MC b7MD b7ME b7MF b7MG b7MH b7MI b7MJ b7MK b7ML b7MN b7MO b7MP b7MQ b7MR b7MS b7MT b7MU b7MV b7MW b7MX b7MY b7MZ b7NA b7NB b7NC b7ND b7NE b7NF b7NG b7NH b7NI b7NJ b7NK b7NL b7NM b7NO b7NP b7NQ b7NR b7NS b7NT b7NU b7NV b7NW b7NX b7NY b7NZ b7OA b7OB b7OC b7OD b7OE b7OF b7OG b7OH b7OI b7OJ b7OK b7OL b7OM b7ON b7OO b7OP b7OQ b7OR b7OS b7OT b7OU b7OV b7OW b7OX b7OY b7OZ b7PA b7PB b7PC b7PD b7PE b7PF b7PG b7PH b7PI b7PJ b7PK b7PL b7PM b7PN b7PO b7PP b7PQ b7PR b7PS b7PT b7PU b7PV b7PW b7PX b7PY b7PZ b7QA b7QB b7QC b7QD b7QE b7QF b7QG b7QH b7QI b7QJ b7QK b7QL b7QM b7QN b7QO b7QP b7QQ b7QR b7QS b7QT b7QU b7QV b7QW b7QX b7QY b7QZ b7RA b7RB b7RC b7RD b7RE b7RF b7RG b7RH b7RI b7RJ b7RK b7RL b7RM b7RN b7RO b7RP b7RQ b7RR b7RS b7RT b7RU b7RV b7RW b7RX b7RY b7RZ b7SA b7SB b7SC b7SD b7SE b7SF b7SG b7SH b7SI b7SJ b7SK b7SL b7SM b7SN b7SO b7SP b7SQ b7SR b7SS b7ST b7SU b7SV b7SW b7SX b7SY b7SZ b7TA b7TB b7TC b7TD b7TE b7TF b7TG b7TH b7TI b7TJ b7TK b7TL b7TM b7TN b7TO b7TP b7TQ b7TR b7TS b7TT b7TU b7TV b7TW b7TX b7TY b7TZ b7UA b7UB b7UC b7UD b7UE b7UF b7UG b7UH b7UI b7UJ b7UK b7UL b7UM b7UN b7UO b7UP b7UQ b7UR b7US b7UT b7UU b7UV b7UW b7UX b7UY b7UZ b7VA b7VB b7VC b7VD b7VE b7VF b7VG b7VH b7VI b7VJ b7VK b7VL b7VM b7VN b7VO b7VP b7VQ b7VR b7VS b7VT b7VU b7VV b7VW b7VX b7VY b7VZ b7WA b7WB b7WC b7WD b7WE b7WF b7WG b7WH b7WI b7WJ b7WK b7WL b7WM b7WN b7WO b7WP b7WQ b7WR b7WS b7WT b7WU b7WV b7WW b7WX b7WY b7WZ b7XA b7XB b7XC b7XD b7XE b7XF b7XG b7XH b7XI b7XJ b7XK b7XL b7XM b7XN b7XO b7XP b7XQ b7XR b7XS b7XT b7XU b7XV b7XW b7XZ b7YA b7YB b7YC b7YD b7YE b7YF b7YG b7YH b7YI b7YJ b7YK b7YL b7YM b7YN b7YO b7YP b7YQ b7YR b7YS b7YT b7YU b7YV b7YW b7YX b7YY b7YZ b7ZA b7ZB b7ZC b7ZD b7ZE b7ZF b7ZG b7ZH b7ZI b7ZJ b7ZK b7ZL b7ZM b7ZN b7ZO b7ZP b7ZQ b7ZR b7ZS b7ZT b7ZU b7ZV b7ZW b7ZX b7ZY b7ZZ

In tablets, the active components are admixed with at least one inert diluent such as lactose, starch, mannitol, microcrystalline cellulose or calcium phosphate; granulating and disintegrating agents for examples corn starch, gelatine, microcrystalline cellulose or polyvinylpyrrolidone; lubricating agents such as magnesium stearate, stearic acid or talc. The tablets may be coated by known techniques to delay disintegration and absorption in the gastrointestinal tract and, thereby, provide a sustained action over a long period. Gastric film-coated or enteric film-coated can be made with sugar, gelatin, hydroxypropylcellulose or acrylic resins.

Formulation for oral use may also be presented as hard capsules of absorbable material, such as gelatin, wherein the active ingredient is mixed with an inert diluent and lubricating agents, or pasty materials, such as ethoxylated saturated glycerides.

Soft gelatine capsules are possible wherein the active ingredient is mixed with water or an oil medium, for example, peanut oil, liquid paraffin or olive oil.

Dispersible powders and granules suitable for preparation of a suspension by the addition of water provide the active ingredient in admixture with dispersing or wetting agent, a suspending agent, such as

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sodium carboxymethylcellulose , sodium alginate, polyvinylpyrrolidone, gum tragacanth, xanthan gum, gum acacia and one or more preservatives, such as methyl or n-propyl-p-hydroxybenzoate. Additional excipients, for example sweetening, flavouring and colouring agents may also be present.

Liquid composition for oral administration include emulsions, solutions, suspensions, syrups and elixirs containing commonly used inert diluents, such as distilled water, ethanol, sorbitol, glycerol or propylene glycol. Such compositions may comprise adjuvants such as wetting agents, suspending agents, sweetening, flavouring, perfuming, preserving agents and buffers.

The pharmaceutical composition of the present invention may also be administered in the form of suppositories for rectal administration of the drug.

The dosage and frequency of dose may vary depending upon symptoms, age and body weight of the patient, as well as upon the route of administration, but in general the composition of the present invention may be administered orally in doses of from 7g to 23g a day to a patient of the average weight of 70kg.

The above composition may be prepared in the form of a kit. Said kit may comprise the composition as such or its components separately prepared, for instance, in the

form of different capsules. In this manner it is possible to combine different compounds and/or their different amount depending on the patient to be treated.

It is therefore a further object of the present invention a kit of parts for sequential, simultaneous or separate administration as recited in the appended claims.

The food composition, the method and the pharmaceutical composition according to this invention will be further described with reference to the examples provided below merely by way of non-restrictive illustration in which the percentages stated are to be understood as percentages by weight of the total dry weight.

EXAMPLE 1

Wheat gluten 55%

Wheat fibre 40%

Vegetable fibres 5%

By wheat fibre is meant the fibre of the wheat stems (one example of a commercially available product is that sold by the name of VITACEL®).

Wheat gluten is a product marketed by various firms such as for example the company Rocchetta (Italy).

The vegetable fibres are for example fibres of tomato, spinach, onion, etc.; these fibres are marketed by various firms, including Newfood (Italia).

EXAMPLE 2

Wheat gluten 35%

Soya proteins 20%

Wheat fibre 45%

An example of a commercially available product comprising soya protein is Soymin®.

EXAMPLE 3

Wheat gluten 35%

Fruit fibres 45%

Soya proteins 20%

The fruit fibres used in this composition were those marketed in Italy under the name VITACEL Arancia® and VITACEL Mela®.

EXAMPLE 4

Wheat gluten	34%
Wheat germ	33%
Wheat fibre	17%
Vegetable fibres	16%

Wheat germ is marketed by various producers, such as for example the company Rizzolio (Italy).

EXAMPLE 5

Milk proteins	10%
Wheat fibre	15%
Wheat germ	60%
Fruit fibres	15%

EXAMPLE 6

The flour in Example 1 was used to prepare pasta. For this purpose the flour was mixed with a sufficient quantity of water to obtain a dough suitable for forming by extrusion (approximately 20 to 30% of water). A pasta in the form of spaghetti was obtained by extrusion through suitable dies and when subsequently cooked in boiling salted water yielded organoleptic properties entirely similar to those of a pasta made with high quality durum wheat semolina.

EXAMPLE 7

The flour in Example 2 was used to prepare bread. For this purpose the flour was mixed with a sufficient

quantity of water to obtain a mouldable dough, and to this a suitable quantity of bread yeast and salt were also added. The dough was then left to rise for approximately 2 hours, mixed again and finally left to stand for approximately 1 hour before being shaped and baked in an oven at approximately 220°C.

The bread obtained in this way had optimum organoleptic properties, crustiness and crumbliness.

The flours in the examples described above are virtually interchangeable and can be used in the preparation of pasta, egg pasta, bread, bread sticks, biscottes, sweet and savoury flans, biscuits, etc., following the addition of suitable additional ingredients.

The only differences which can be found between the various flours lie in their different carbohydrate contents, which for example are lowest in the flour according to Example 1 (definitely below 5%) and tend to be higher (although always below 15%) in the flours containing fruit or vegetable fibres, on account of the residual glucide content of those fibres.

As a consequence a person who wishes to lose weight by following the method according to this invention should initially use flours such as those in Examples 1 or 2, which guarantee an absolutely negligible glucide

content.

Once the ideal weight has been gained the individual can alternate the use of the abovementioned flours with those of flours (such as those in Examples 3 and 4) which have a certain, though low, glucide content due to the fruit or vegetable fibre content.

Once the individual's weight and form have become stabilized, then flours containing other ingredients such as milk proteins, dried meat or fish animal proteins, powdered milk, powdered cream, whole eggs or dried albumin or dried egg yolk only can also be introduced into the diet.

In this latter stage the carbohydrate content should however always be maintained below 20% by weight.

It should be pointed out that the flours according to the invention constitute the basis of the food intake of an individual who intends to improve his appearance by eliminating excess kilos using the method according to this invention. Provided that all carbohydrate-based foods are replaced by similar foods prepared using the flours according to the invention the individual can nevertheless consume a variety of foods rich in proteins and/or lipids (meat, fish, delicatessen products, cheeses) without any limit on quantity and without in any way prejudicing the result achieved, or losing excessive

weight.

This constitutes an enormous advantage in comparison with the low-calorie diet regimes proposed hitherto, which presuppose a considerable propensity to "sacrifice" on the part of individuals who subject themselves to them, and which for this reason have therefore as a result achieved very low compliance on the part of such individuals.

In addition to imposing no quantitative limits on food intake, the method according to the invention makes it possible to vary foods consumed with great freedom, which further increases the willingness of individuals to follow the proposed diet regime satisfactorily.

The following examples relate to pharmaceutical compositions according to the present invention. The following compositions are preferably prepared in the form of a gelatine capsule.

EXAMPLE 8

Preparation of a gelatine capsule. The following components are admixed, optionally with suitable excipients to reach the capacity of the capsule: the capsule is then filled and sealed.

Diethylpropione chlorohydrate	mg.	20
Fenfluramine	mg.	4

Benfluorex	mg.	50
Triiodotiracetic acid	mg.	0,4
Pancreatine IX F.U.	mg.	120
Metformine	mg.	200
Na dehydrocolate	mg.	40

EXAMPLE 9

Preparation of two capsules A and B which are part of a kit and which comprise different components to take in combination.

Capsule A

Fenfluoramine	mg.	4
Benfluorex	mg.	50

Capsule B

Triiodotiracetic acid	mg.	0,8
Pancreatine IX F.U.	mg.	240
Metformine	mg.	370
Na dehydrocolate	mg.	80
Dipotassium chlorazepate	mg.	2

EXAMPLE 10

Preparation of a capsule A and a capsule B which are part of a kit and which comprise different compounds to take in combination.

Capsule A

Diethylpropione chlorohydrate	mg.	35
Benfluorex	mg.	150

Vit. C mg. 100

Vit. E mg. 100

Vit B₆ mg. 50

Capsule B

Pancreatine IX F.U. mg. 240

Metformine mg. 370

Na dehydrocolate mg. 80

Dipotassium chlorazepate mg. 4

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